REMARKS

This amendment is submitted in response to the final Office Action mailed on June 16, 2005. Claims 1, 3-25 are pending in this application. Claim 2 was previously canceled. In the Office Action, Claims 3-4 are rejected under 35 U.S.C. §112, second paragraph, Claims 1, 5, 16, 22 and 25 are rejected under 35 U.S.C. §102 and Claims 1, 5 and 14-25 are rejected under 35 U.S.C. §103. In response Claims 3-4 have been amended. This amendment does not add new matter. In view of the amendments and/or for the response set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 3-4 are rejected under 35 U.S.C. §112, second paragraph. In response, Applicants have amended Claims 3-4 to correct the informalities cited by the Patent Office. Accordingly, Applicants respectfully request that the rejection of Claims 3-4 under 35 U.S.C. §112, second paragraph, be withdrawn.

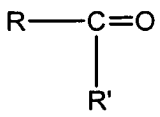
In the Office Action, Claims 1 and 5 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,618,955 to Mechoulam et al. ("*Mechoulam*"). Claims 1, 5, 16, 22 and 25 are rejected under 35 U.S.C. §102(b) as anticipated by WO 96/37200 to Stordy et al. ("*Stordy*"). Applicants respectfully disagree with and traverse these rejections for at least the reasons set forth below.

Independent Claim 1 recites, in part, a composition for oral administration comprising a naturally occurring precursor that is metabolised to a compound having anandamide activity for use as a medicament. Independent Claim 16 recites, in part, a method of treating an anandamide-mediated ailment which comprises administering to a patient having an anandamide-mediated ailment an effective amount of a composition comprising a naturally occurring precursor that is metabolised to a compound having anandamide activity for use as a medicament, wherein the precursor comprises an LCPUFA which is a polyunsaturated fatty acid of 16-28 carbon atoms having from 2 to 6 double bonds, and having a moiety selected from the group consisting of methylated-, branched-, cyclic-, conjugated-, non-methylene interrupted-, epoxy-, furanoid-, hydroxyl-, allylic-, trans-, and seleno. Applicants respectfully submit that *Mechoulam* fails to disclose or suggest every element of Claim 1. Further, *Stordy* fails to disclose or suggest every element of Claims 1 and 16.

Mechoulam is directed to polyunsaturated fatty acid amides and their derivatives, which are themselves final synthesis or end products. See, *Mechoulam*, column 1, lines 10-16. The compounds exhibit physiological activity and are useful as active ingredients in pharmaceutical compositions for the treatment of several diseases. Nevertheless, *Mechoulam* is entirely directed to the use of final synthesis or end products, namely, the polyunsaturated fatty acid amides and their derivatives and not any to any compounds utilizing the intermediates or precursors for forming these polyunsaturated fatty acid amides.

Claim 1 is directed to compositions utilizing a precursor (e.g. intermediate) that is metabolized to form a compound having anandamide activity. For example, the precursor can be metabolized endogenously or within the human body to form a compound having anandamide activity. In contrast, *Mechoulam* discloses compounds that exhibit anandamide activity that are already in their final form prior to entering the body. Consequently, *Mechoulam* fails to disclose or suggest the presently claimed precursors that are metabolised to a compound having anandamide activity and used as active compounds in a nutritional composition as required by the present claims.

Moreover, Applicants respectfully disagree with the Patent Office's assertion that the Claim 1 is drawn toward an unidentified, non-existent precursor in a composition for oral administration. See, Office Action, page 6. For example, Claim 1 recites, in part, that the precursor comprises a long chain polyunsaturated fatty acid (LCPUFA) which is a polyunsaturated fatty acid of 16-28 carbon atoms having from 2 to 6 double bonds, and having a moiety selected from the group consisting of methylated-, branched-, cyclic-, conjugated-, non-methylene interrupted-, epoxy-, furanoid-, hydroxyl-, allylic-, trans-, and seleno, or a LCPUFA or derivative thereof of the general formula X:



wherein R is the alkenyl moiety of the LCPUFA of total chain length 16-28 carbon atoms with 2-6 double bonds, with the first double bond at the c-1, c-3 c6, c7, c9 c12 position, counting

from the non carboxyl (methyl) part of the molecule; and where R" is selected from the group consisting of -H, lower alkyl, -OH, NH_3, $NHCH_2CH_2OH$, and an acid addition salt or complex thereof. Thus, Applicants have identified specific compounds that can be precursors for the claimed composition.

Stordy is directed to a method for preparing a composition to be used for treating disorders such as dyslexia, inadequate night vision or dark adaptation. These compounds are described as containing, among other things, docosahexanoic ("DHA"). See, *Stordy*, page 1. However, contrary to the Patent Office's assertions, independent Claims 1 and 16 do not even recite DHA. Moreover, *Stordy* is directed to DHA, which is a non-modified polyunsaturated acid. Consequently, *Stordy* fails to disclose or suggest the presently claimed composition for oral administration comprising a naturally occurring precursor that is metabolised to a compound having anandamide activity, and specifically, the precursors having the moieties detailed in independent Claims 1 and 16.

As further evidence, Applicants have submitted an affidavit under 37 C.F.R. §1.132 ("*Affidavit*" attached hereto as Exhibit A). Applicants respectfully assert that the *Affidavit* properly obviates the anticipation rejections of the pending claims with respect to the cited references. In this regard, the *Affidavit* sufficiently and properly evidences the deficiency of *Mechoulam* and *Stordy* with respect to the present claims. For the example, the *Affidavit* provides further support to show that the cited references fail to disclose or suggest a composition for oral administration comprising a naturally occurring precursor that is metabolised to a compound having anandamide activity.

For the reasons discussed above, Applicants respectfully submit that Claims 1 and 16 and Claims 5, 22 and 25 that depend from these claims are novel, nonobvious and distinguishable from the cited reference. Accordingly, Applicants respectfully request that the rejections of Claims 1, 5, 16, 22 and 25 under 35 U.S.C. §102(b) be withdrawn.

In the Office Action, Claims 1, 5 and 14-25 are rejected under 35 U.S.C. §103 as being unpatentable over *Mechoulam* in view of *Stordy* further in view of the combination of U.S. Patent No. 5,874,459 to Makriyannis et al. ("*Makriyannis*") in view of WO 94/28913 to Kyle et al. ("*Kyle*"). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

The present claims pertain, in part, to the provision of an agent that is suitable for the treatment of a variety of different diseases without give rise to known side affects such as nausea or cramping. Additionally, the agent may be easily incorporated by an individual. Thus, the present invention provides naturally occurring precursors that are metabolized to a compound exhibiting anandamide activity. Surprisingly, Applicants have found that a composition containing such an agent may be useful for the treatment of a variety of diseases.

As discussed previously, *Mechoulam* and *Stordy* are deficient with respect to the present claims. For example, the compounds specified in *Mechoulam* are final synthesis or end products and thus not identical to the polyunsaturated acid precursors or intermediates of the present claims. *Mechoulam* also fails to disclose or suggest that any such precursor or intermediates used for the synthesis of the respective acid amides should be incorporated in a nutritional composition.

Stordy and *Kyle* merely specify the use of non-modified polyunsaturated acids like DHA or ARA. They fail to disclose that the polyunsaturated acids have an additional residue or moiety as required, for example, by Claim 1. *Makriyannis* is directed to a method for inhibiting anandamide amidase in an individual or animal and novel inhibitors of anandamide amidase. *Makriyannis* fails to disclose or suggest a composition for oral administration comprising a naturally occurring precursor that is metabolised to a compound having anandamide activity being used as active compounds according to the claimed invention. In fact, *Makriyannis* relates to a completely different objective because the compounds specified therein are compounds capable of inhibiting the degradation of anandamide by inhibiting the enzyme anandamide amidase, which teaches away from the claimed invention. See, *Makriyannis*, column 3, lines 38-60. The present claims pertain to precursors that are metabolized to a compound exhibiting anandamide activity. This difference in mode of action explains the different chemical structures of the compounds used in *Makriyannis*. Consequently, there is no evidence that the composition in *Makriyannis* may successfully be used for the specific purpose of the claimed invention.

For the reasons discussed above, the combination of *Mechoulam* in view of *Stordy*, *Makriyannis* and *Kyle* does not teach, suggest, or even disclose the claimed invention, and thus, fails to render the claimed subject matter obvious for at least these reasons.

Accordingly, Applicants respectfully request that the obviousness rejection with respect to Claims 1, 5 and 14-25 be reconsidered and the rejection be withdrawn.

Finally, the Patent Office has not provide support for an objection or rejection of Claims 3-4 and 6-13. Applicants respectfully submit that these claims are allowable for at least the reasons set forth above.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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